REMARKS

The Specification was amended to correct minor typographical errors. A marked-up version of the amended section is attached. Claims 1-3, 6-29 and 32-45 were pending in this application. Claims 1, 2, 6, 10, 11, 14, 17-20, 23, 26-28 and 32 were amended, claims 21, 22, 24 and 25 were canceled and claims 7-9 and 33-45 were withdrawn from consideration. Thus claims 1-3, 6, 10-20, 23, 26-29 and 32 are still pending in the present application and under consideration. Applicant maintains that the amendments do not introduce any new matter.

Declaration

A new Declaration in compliance with 37 CFR 1.67(a) will be submitted as soon as we obtain the inventor's signature on it.

Objection to the Disclosure

The Examiner objected to the disclosure because of informalities in Table 2 (second and third columns). In particular, the Examiner objected to the term "10 g/mL" that appears twice in the second and third columns. In response, applicant has amended Table 2 to correct a typographical error and thereby change the above term in the second and third columns to 10μM and 100μM respectively.

Rejection under 35 U.S.C. 112, Second Paragraph

The Examiner alleges that claims 6 and 32 are confusing as containing more than one species elected for prosecution. In response, applicant has amended claims 6 and 32 to cancel non elected species from these claims. Accordingly, the Examiner is kindly requested to withdraw this rejection.

The Examiner also rejected claim 11 because it recites claim 4 which has been canceled. In response, applicant has amended claim 1 to make it dependent from claim 1. Accordingly, the Examiner is kindly requested to withdraw this rejection.

The Examiner further rejected claims 13 and 32 by indicating that the recitation on line 7 should be "(c)". In response, the various steps in claim 32 were deleted and thus the rejection of this claim is rendered moot. In addition, applicant indicates that the version of the claim 13 in the previous Amendment contains a typographical error where "c" was inadvertently was typed as "a". The original claim 13 did not contain this error. Since this claim was not amended and is still in its original form, no correction is warranted beyond having the correct version of the claim in the current Amendment. Accordingly, the Examiner is kindly requested to withdraw this rejection.

The Examiner also rejected claim 14 as indefinite for reciting the term "pre-selected". In response, applicant has amended claim 14 to delete the term "pre-selected". Accordingly, the Examiner is kindly requested to withdraw this rejection.

The Examiner further rejected claim 18 because it lacks the antecedent basis "method of claim 18". In response, it appears that claim 19 was intended by this rejection rather than claim 18. Therefore, applicant has amended claim 19 to correct the antecedent basis. Accordingly, the Examiner is kindly requested to withdraw this rejection.

Rejection under 35 U.S.C. 112, First Paragraph

The Examiner claims 1-3, 6, 10-29 and 32 are rejected under 35 USC 112, first paragraph, enablement requirement. The Examiner's argument focuses on i) the breadth of the claims relative to

the preferred embodiment of using catalytic antibodies to modify biologically active molecules and ii) the lack of working examples.

Applicant respectfully traverses. As admitted by the Examiner, the Specification provides extensive disclosure of the methods of making and using catalytic antibodies, as well as target molecules to be modifies by disclosed antibodies. Every stage of the process is disclosed in a great detail therefore enabling a person of ordinary skill in the art to practice the claimed invention without undue experimentation. The disclosure also teaches how to test the antibodies for the desired activity. The fact that the specification does not provide working examples of the elicitation of catalytic antibodies does not support the Examiner's rejection. Working examples are not required to satisfy the enablement requirement (MPEP Section 2164.02).

The Examiner notes that specification teaches that catalytic antibody can be identified by screening human phage antibody display libraries against an antibiotic-target conjugate but also states that it is not clear why this procedure would work (Office Action page 7). Applicant urges that the specification is quite clear in this respect. The specification teaches selecting labels that exhibit a low but detectable reaction with the desired target in the absence of a catalyst, for example, the conjugation reaction of β-lactam antibiotics with proteins (Specification, page 9, line 15 – page 10, line 10). The same passage in the specification also notes that the fact that the uncatatalyzed reaction can occur at a slow rate places a lower burden on the catalyst and may only require that the catalyst bind to both the target and label so as to hold them in close proximity and increase their effective concentrations. In addition, the specification is not limited to selection of catalytic antibodies by panning phages and also teaches a variety of other approaches including directed evolution under selective pressure and/or the utation of catalysts with similar chemical activities but different structural specificity.

Applicant submits that one of ordinary skill in the art would be able to practice the presently claimed subject matter in view of the specification and the prior art without undue experimentation. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). See also, MPEP § 2164.01. The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983); *M.I.T. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). See also, MPEP § 2164.01.

Contrary to the Examiner's suggestion, the specification need not provide examples or specific description of embodiments for the entire scope of the invention. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention [MPEP §2164]. A patent does not teach, **and preferably omits**, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). [See also, MPEP § 2164.01].

With respect to the breadth of the claims, Applicant urges that the claims as currently amended are fully enabled. Although the specification discloses an embodiment in which a β-lactam antibiotic is attached to a target molecule, the teachings of the specification are considerably broader. The section of the specification "labels" for modifying target molecules (Specification, page 8, line 22 – page, line 10) lists a variety of suitable labels for use with the methods of the invention and also describes properties of the labels that can be used to select for other suitable labels.

The Examiner also rejected claims 1-3, 6, 10-29 and 32 are rejected under 35 USC 112, first paragraph, written description requirement.

Applicant respectfully traverse and urge that the Examiner misinterprets the legal standards of the written description requirement of 35 USC 112, first paragraph. Applicant submits that the "enablement" prong of the first paragraph of 35 U.S.C. §112 is separate and distinct from the "written description" requirement of the first paragraph of 35 USC 112. See, MPEP Section 2161. It appears that the Examiner is confusing the "written description" and the "enablement" prongs of the 35 U.S.C. 112, first paragraph.

With respect to the "written description" prong, Applicant submits that the function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 U.S.P.Q. 620 (CCPA 1973). Therefore, the test for written description under 35 U.S.C. §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill that Applicant had possession of the subject matter later claimed. *In re Kaslow*, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). [See also, MPEP, Section 2163.02].

The Examiner's attention is further drawn to the US PTO "SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES" (the US PTO's website). In these guidelines, Example 16 is directed specifically to antibodies. The example provides that where the antigen is disclosed in the Specification, the disclosure meets the requirement under 35 USC 112, first paragraph for the claimed antibody.

Thus, one of ordinary skill in the art would readily recognize from the original disclosure that Applicant invented the presently claimed subject matter. Applicant submits that the Examiner's

allegation that the specification is deficient in that it does not show working examples is not relevant to a determination of whether applicant has satisfied the written description requirement of the first paragraph of 35 USC 112. Therefore, applicant requests that this rejection be withdrawn.

Rejection under 35 U.S.C. 102

The Examiner rejected claims 1-2, 6, 17-18, 27-29 and 32 under 35 USC 102(b), as allegedly being anticipated by Schochetman at al. The Examiner also rejected claims 1-3, 6, 11-12, 17-21, 27-29 and 32 under 35 USC 102(b), as allegedly being anticipated by Davis et al. The Examiner further rejected claims 1-2, 6, 11-12, 17-18, 20-21, 27-28 and 32 under 35 USC 102(b), as allegedly being anticipated by Tanaka et al. The Examiner also rejected claims 1-3, 6, 17-19, 27-29 and 32 under 35 USC 102(b), as allegedly being anticipated by either of Landry, Blackburn or Shuster.

These rejections will be addressed together.

In response, applicant urges that as clearly stated in the MPEP:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[MPEP 2131]

Applicant urges that none of the cited references disclose all elements of the currently pending claims.

Applicant has amended the claims to more clearly define the invention. Currently amended claims are directed to modifying target molecules by attaching a label. Attaching the label to the target molecule modulates an activity of the target molecule, deactivates the target molecule; or targets said target molecule for degradation or clearance. The term 'label' is defined in the Specification and is specifically defined to exclude water. (Specification, pages 6, 8-10). "The term 'labeling' is used

broadly to describe the attachment of chemical groups or moieties other than water to a target substance." (Specification, page 6)

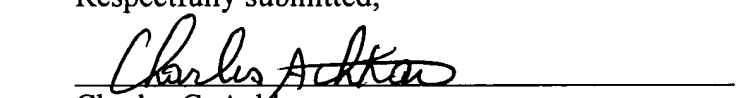
Further, term 'modification' is defined in the Specification and does not include hydrolysis. (Specification, page 6). Currently pending claims must be interpreted in view of the disclosure in the specification. Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.' *In re Marosi*, 710 F.2d 799, 802 (Fed. Cir. 1983).

The cited references teach neither catalysis of the attachment of a label to a target nor the use of this labeling reaction to alter the activity of the target or to cause the target to be degraded or cleared. As noted above, in the examples cited by the Examiner that involve hydrolysis reactions, the water molecule required in the hydrolysis reaction cannot be equated with the label disclosed in the specification. Thus, the cited references do not teach or suggest all limitations of the currently pending claims. Accordingly, the Examiner is kindly requested to withdraw these rejections.

In view of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

Dated: November 7, 2005

Respectfully submitted,



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